REMARKS

This Application has been carefully reviewed in light of the Final Office Action mailed August 23, 2005. At the time of the Final Office Action, Claims 22-66 were pending in this Application. Claims 22-66 were rejected. Claim 40 has been amended to provide proper antecedent basis. Claim 36 has been canceled without prejudice or disclaimer. Applicants respectfully request reconsideration and favorable action in this case.

Double Patenting Rejection

Claims 22-39 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 21-29, 33 and 34 of U.S. Patent 6,742,517 issued to Mark R. Frye et al. ("517-Frye") in view of U.S. Patent 5,357,758 issued to Martin D. Andonian ("Andonian") and U.S. Patent 6,446,630 issued to Oliver E. Todd, Jr. ("Todd"), and further in view of U.S. Patent 4,211,086 issued to Rex D. Leonard et al. ("Leonard").

Applicants enclose a Terminal Disclaimer and required fee in compliance with 37 C.F.R. 1.321 to overcome these rejections. The instant application and 517-Frye patent are commonly owned by Mallinckrodt, Inc. This instant application is a continuing application of 517-Frye.

Rejections under 35 U.S.C. § 112

Claim 36 was rejected by the Examiner under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Applicants have canceled Claim 36 without prejudice or disclaimer.

Amendment to Claim 40 does not require a new search and should therefore be entered.

As shown above, Claim 40 was amended merely to provide proper antecedent basis. In particular, the limitation "a portable-unit oxygen gas transfer connector for transferring oxygen gas to an oxygen gas delivery device for delivery" was moved upward such that proper antecedent basis is provided for the limitation "a conserving device for LOX conservation which provides oxygen gas to said portable-unit oxygen gas transfer connector

..." Thus, Applicants submit that no substantive amendment has been made that would require a new search. Therefore, Applicants respectfully request that the amendment to Claim 40 be entered.

Rejections under 35 U.S.C. §103 should be withdrawn.

Claims 40-66 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Andonian* in view of *Todd* and further in view of *Leonard*.

In order to establish a *prima facie* case of obviousness, the references cited by the Examiner must disclose all claimed limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Furthermore, according to § 2143 of the Manual of Patent Examining Procedure, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

In this instance, the Examiner has not established a *prima facie* case of obviousness for at least the following reasons:

- (a) The proposed combination of *Andonian*, *Todd*, and *Leonard* fails to teach or suggest all of Applicants' claimed limitations; and
- (b) The Examiner has not shown the required suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine *Andonian*, *Todd*, and *Leonard* to arrive at the limitations recited in Applicants' claims.

A. The proposed combination of *Andonian*, *Todd*, and *Leonard* fails to teach or suggest all of Applicants' claimed limitations.

"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." M.P.E.P. § 2143.03 (citing In re Royka, 490

F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974)) (emphasis added). "All words in a claim must be considered in judging the patentability of that claim against the prior art." M.P.E.P. § 2143.03 (quoting *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970)).

With respect to independent Claim 40, the Examiner acknowledges that the proposed combination of Andonian, Todd, and Leonard "teach essentially all of the limitations except for the liquid withdrawal warming coil located externally of the portable LOX container and the conserving device being integrated into the LOX apparatus." (Final Office Action, page 4) (emphasis added). Thus, the Examiner explicitly admits that the cited art does not teach or suggest all the limitations recited in Claim 40, which necessarily precludes a showing of prima facie obviousness, according to M.P.E.P. § 2143.03 and the Federal Circuit.

After acknowledging that the cited art does not teach "the liquid withdrawal warming coil located externally of the portable LOX container and the conserving device being integrated into the LOX apparatus," the Examiner explains:

. . . However, Applicant has not provided criticality in the specification as originally filled [sic] for these particular arrangements. One of ordinary skill in the art would have expected the above combination to function equally as well. Furthermore, Applicant has not provided a reasoned statement as to how the recited arrangement solves a stated problem, provides an advantage over the prior art or provides unexpected results.

(Final Office Action, page 4)

Applicants submit that these arguments by the Examiner are irrelevant to the obviousness determination. First, the Examiner argues that "Applicant has not provided criticality in the specification as originally filled [sic] for these particular arrangements." However, Applicants submit that there is no requirement to explain the criticality of particular claim limitations or "arrangements" in the specification or otherwise. Applicants request that the Examiner indicate a statute or other law requiring an applicant to explain the criticality of claim limitations that -- as admitted by the Examiner -- are not taught or suggested by the prior art. As discussed above, the M.P.E.P. and Federal Circuit explicitly state that a showing of obviousness requires that "all the claim limitations must be taught or suggested by the prior art."

Second, the Examiner argues that "[o]ne of ordinary skill in the art would have expected the above combination to function equally as well." Again, Applicants submit that this assertion -- regardless of whether it is true -- is irrelevant to the obviousness determination. Applicants request that the Examiner indicate the statute or other legal basis for rejecting a claim because a combination of references that fails to disclose particular limitations of the claim may "function equally as well" as the claimed invention. M.P.E.P. § 2144.04(II) explains that omission of an element and its function in the claim at issue, as compared to the cited reference(s), is obvious if the function of the element is not desired. However, the present situation is the opposite -- here, the cited references omit elements recited in the claim at issue (as admitted by the Examiner). Thus, M.P.E.P. § 2144.04(II) does not apply. Again, the well-established rule of law is that a showing of obviousness requires that "all the claim limitations must be taught or suggested by the prior art."

Third, the Examiner argues that "Applicant has not provided a reasoned statement as to how the recited arrangement solves a stated problem, provides an advantage over the prior art or provides unexpected results." However, such statements are relevant for rebutting a prima facie showing of obviousness, not for establishing a prima facie showing of obviousness. In other words, the Examiner cannot use the absence of such statements by the Applicants to establish a prima facie showing of obviousness, particularly when the Examiner has explicitly admitted that the cited references to not teach or suggest all of the limitations recited in Claim 40. If the Examiner wishes to maintain his position regarding this requirement, Applicants request that the Examiner indicate the statute or other legal basis for rejecting a claim -- based on a combination of references that fails to disclose particular limitations of the claim -- because the applicant has not provided evidence that the recited arrangement "solves a stated problem, provides an advantage over the prior art or provides unexpected results."

However, although Applicants believe such statement is not necessary or relevant to the obviousness determination (particularly here, where the Examiner has explicitly admitted that the cited art does not teach or suggest all the limitations recited in Claim 40), Applicants will provide such statement. With respect to the limitation "said liquid withdrawal warming coil located externally of said portable LOX container," Applicants submit that such

arrangement provides greater heat transfer between the external environment and the fluid within the warming coil as compared to arrangements in which the warming coils are located within the LOX container. Such increased heat transfer is advantageous in at least some situations and/or applications.

B. The Examiner has no shown a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine *Andonian*, *Todd*, and *Leonard* to arrive at the limitations recited in Applicants claims.

Even assuming for the sake of argument that the proposed Andonian-Todd-Leonard combination did disclose, teach or suggest the combination of limitations recited in Claims 40-66 (which Applicants do not agree), the proposed Andonian-Todd-Leonard combination is improper. In particular, the Examiner has not shown the required suggestion or motivation to combine Andonian, Todd, and Leonard. To establish a prima facie case of obviousness, the Examiner must show, among other things, some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. M.P.E.P. § 2142. (emphasis added) "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." M.P.E.P. § 2143.01. (emphasis added)

For example, regarding the proposed combination of *Andonian* and *Todd*, the Examiner merely states:

"Andonian does not specifically teach a conserving device for LOX conservation which provides oxygen gas to said portable unit oxygen gas transfer connector. However, Todd, Jr. does teach the use of a conserving device so that there is not a waste of oxygen as there would be if the oxygen were supplied continuously (See Col. 1, lines 64-67 and Col. 2, lines 1-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a conserving device in the LOX apparatus of Andonian as disclosed by Todd, Jr. so that oxygen is not wasted and is conserved." (Office Action, page 3).

Thus, the Examiner merely states that although Andonian does not teach a conserving device, Todd does teach a conserving device, and thus it would have been obvious to modify Andonian to include a conserving device. Such conclusory reasoning clearly fails to meet the requirement for combining references, as set out in the M.P.E.P. In particular, the Examiner

presents no suggestion or motivation in either *Andonian* or *Todd* to combine the two references. *See* M.P.E.P. §§ 2142 and 2143.01. Applicants thus assume that the Examiner's assertion that the proposed combination "would have been obvious" is based merely on speculation in hindsight, which is insufficient for supporting a modification or combination of references, under both the M.P.E.P.² and governing Federal Circuit case law.³

As another example, regarding the proposed combination of *Andonian-Todd* with *Leonard*, the Examiner merely states:

"Andonian/Todd, Jr. teach essentially all of the limitations except for a demand flow control device coupled to a conserving device for adjustment of gas flow from said container to said delivery device. However, Leonard et al in a LOX breathing system teaches a demand flow control device 43,68 so that the user can control the flow of oxygen gas that is to be consumed. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a demand flow control device as taught by Leonard et al so that the user can control the flow of oxygen gas that is to be consumed." (Office Action, pages 3-4).

Thus, the Examiner merely states that although Andonian-Todd does not teach a demand flow control device, Leonard does teach a demand flow control device, and thus it would have been obvious to modify Andonian-Todd to include a demand flow control device. As discussed above, such conclusory reasoning clearly fails to meet the requirement for

¹ If the Examiner is relying on "common knowledge" or "well known" art in support of his rationale for combining the references, the Examiner is requested to produce a reference in support of his position pursuant to M.P.E.P. § 2144.03. If the Examiner is relying on personal knowledge to supply the required motivation or suggestion to combine, Applicants respectfully request that the Examiner produce an affidavit supporting such facts pursuant to M.P.E.P. § 2144.03.

² See M.P.E.P. § 2145 X.C. ("The Federal Circuit has produced a number of decisions overturning obviousness rejections due to a lack of suggestion in the prior art of the desirability of combining references.)

³ For example, in *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999), the Federal Circuit reversed a finding of obviousness by the Board of Patent Appeals and Interferences, explaining that evidence of a suggestion, teaching, or motivation to combine is essential to avoid impermissible hindsight reconstruction of an applicant's invention:

Our case law makes clear that the best defense against the subtle but powerful attraction of hind-sight obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight.

¹⁷⁵ F.3d at 999 (quoting W.L. Gore & Assoc., Inv. v. Garlock, Inc., 721 F.2d 1540, 1553 (Fed. Cir. 1983)) (emphasis added) (citations omitted).

combining references, as set out in the M.P.E.P. In particular, the Examiner presents no suggestion or motivation in any of *Andonian*, *Todd*, or *Leonard* to combine the three references. *See* M.P.E.P. §§ 2142 and 2143.01. Again, Applicants can only assume that the Examiner's assertion that the proposed combination "would have been obvious" is based merely on speculation in hindsight, which is insufficient for supporting a modification or combination of references, under both the M.P.E.P. and governing Federal Circuit case law, as discussed above.

For at least these reasons, Applicants respectfully request the Examiner withdraw the rejections of Claims 40-66 under 35 U.S.C. §103(a).

Revocation and Power of Attorney/Change of Correspondence Address

Applicants enclose a Revocation and Appointment of Attorney herewith, and respectfully request that all papers pertaining to the above-captioned patent application be directed to Customer No. 31625 and all telephone calls should be directed to Eric M. Grabski at 512.322.2689.

CONCLUSION

Applicants have now made an earnest effort to place this case in condition for allowance in light of the amendments and remarks set forth above. Applicants respectfully request reconsideration of Claims 22-35 and 37-66.

Applicants enclose a check in the amount of \$130.00 for the Terminal Disclaimer fee. Applicants believe there are no additional fees due at this time, however, the Commissioner is hereby authorized to charge any fees necessary or credit any overpayment to Deposit Account No. 50-2148 of Baker Botts L.L.P.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicants' attorney at 512.322.2689.

Respectfully submitted, BAKER BOTTS L.L.P. Attorney for Applicants

Eric M. Grabski Reg. No. 51,749

SEND CORRESPONDENCE TO: BAKER BOTTS L.L.P. CUSTOMER ACCOUNT NO. **31625** 512.322.2689 512.322.8320 (fax)

Date: November 23, 2005